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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,328	08/13/2001	Ilya Raskin	29155/37272	8759

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MARSHALL, GERSTEIN & BORUN
6300 SEARS TOWER
233 SOUTH WACKER
CHICAGO, IL 60606-6357

EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/929,328

Applicant(s)
Raskin et al.

Examiner
Vera Afremova

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1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 14, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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DETAILED ACTION

Claims 1-26 are pending and under examination.

Specification

The disclosure is objected to because of the following informalities:

Specification should not contain empty spaces wherein some particular information was intended but not incorporated, for example: see page 22, par. 3. Appropriate correction is required.

Claim Objections

Claim 22 is objected to because of the following informalities:

All Latin names of biological materials or plants should be italicized. Appropriate correction is required.

Only the genus name of a plant is written starting with capital letter, for example: “*Atropa belladonna*” (line 2) or “*Gratiola officinalis*” (line 3) or other similar occurrences further down. Appropriate corrections are required for the whole claimed list of plants in order to properly indicate where the generic plant species are intended and where the particular plant species are intended.

The claimed list of plant contains several typing errors such as omission of coma (on page 89 in the claim 22, line 18) or insertion of period sign in place of coma (in the claim 22 on page 91, lines 13-14). Some plant names have errors, for example: “Lab lab purpurea” (page 90, line 3). Appropriate corrections are required for the whole claim.

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Claim Rejections - 35 USC § 112

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite, confusing and incomplete because the claimed invention is intended to result in a possession of “a compound having therapeutic activity” but the claimed method does not comprise any recovery step. Claim 1 is also indefinite because “a compound” of step b) does not appear to find an antecedent basis in this claim by the virtue of article “a” and because none of characteristics of “a compound” of step b) are indicated in the method of claim 1.

Claims 1 and 23 is rendered indefinite by the phrases “effective amounts” because neither effects of acetic acid nor particular amounts of acetic acid are indicated in the claimed method. With respect to claim 1 it is also uncertain as claimed and as disclosed whether “effective” amounts are different in order to “induce” production of a compound of interest and in order to “improve” production of a compound of interest.

Claim 1 and 23 are rendered indefinite by the phrase “allowing” because it is unclear what is encompassed by this phrase as claimed. It is unclear what is actually done in order to allow acetic acid to induce or to improve production of a compound of interest by plant besides contacting plant with acetic acid. With respect to claim 1 it is also uncertain as claimed and as intended whether the same protocol allows for induction of the production of a compound of interest and for improvement in the production of a compound of interest.

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With respect to claim 23 it is uncertain as claimed whether some difference or relationship between “compound” and “component” is intended and what it would be, if any.

Claims 2 and 26 are indefinite with regard to acetic acid concentration because it is uncertain whether the amounts expressed in “%” are intended for weight or volume. It is not particularly clear as claimed whether the claimed concentration is a final concentration in a system comprising plant and acetic acid or whether the claimed concentration is a concentration of a contacting composition/solution.

Claim 3 is indefinite because it recites the limitation “the aqueous medium” but there is insufficient antecedent basis for this limitation in the claimed method.

Claim 4 and 5 are indefinite with regard to limitation “an aqueous medium” because it is uncertain whether some differences are intended. Further, it is uncertain as claimed and as disclosed what differences are intended between “exuding” and “extracting” particularly in view when “extracting” is “macerating” (claim 5).

Claim 10 recites the limitation “compounds recovered from the aqueous medium” in the claimed method. There is insufficient antecedent basis for this limitation in the claim lacking limitations drawn to a recovering step and to the use of an aqueous medium.

The whole cluster of claims 11-21 lacks antecedent basis in the method of claim 1. The cluster of claims 11-21 appears to further extend rather than further limit the claimed invention. For example: claim 21 lacks antecedent basis for “the step of extracting”. Claim 12 lacks antecedent basis for “the media”. Claim 17 lacks antecedent basis for “the solvent solution”.

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Claims 11, 15, 16 and 17 are indefinite because it is uncertain what is relationship between limitations drawn to the use of “solvent”, “medium”, “solvent solution” and the use of “acetic acid”. Is “acetic acid” (claim 1) is intended for organic solvent mixture (see claims 15 and 16) or for medium (claim 12) or for solvent solution (claims 17-21)? Further, the limitations of claim 21 such as “a medium” and “an agent” are further adding to the whole confusion of the claims 11-21 because the structural relationship between the use of acetic acid in order to improve production of “a compound” and “an agent” in the solution can not be determined as claimed and as disclosed by applicants.

Claim 22 is indefinite and has improper Markush group. It is suggested to write, for example: “selected from the group consisting of A, B, C and D”. MPEP 2173.05 (h). In addition to several typing errors in names and punctuation as explained above which create some confusion, this claim repeats the same members at least twice, for example: see “*Aesculos woerlitzensis*” (page 89, claim 22, line 10 and lines 15-16) or “*Thymus carnosus*” (page 89, claim 22, line 20 and line 2), etc. The use of quotation marks for some terms following the Latin names is uncertain, for example: see “lemons” (last line on page 89) or “oregano” (page 90, line 1), etc. The use of parentheses encompassing terminology in the claims is indefinite by itself because it is unclear if what is stated in parentheses is a further limitation or simply alternative meaning. In addition, the meaning of terms “wild”, “old”, “young” (page 90, lines 7, 22 and 23) and the meaning of “H2O” and “Acetic Acid” (page 90, lines 14-15) is unclear in the claim.

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Claim 25 is indefinite because it appears to further extend the claimed invention rather limit. The present invention appears to be drawn to a treatment of plant or plant material including "cuticular material" rather than to the use of insect material such as "epicuticular" material. The specification does not comprise definitions with regard to "epicuticular" material. According to Webster's definitions "epicuticle" is an insect exoskeleton material.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,374,627

[A].

Claim is directed to a method for eliciting a compound having therapeutic activity from a plant or plant part wherein the method comprises the step of contacting a living plant or plant part with an effective amount of acetic acid and step of allowing the acetic acid to induce or to improve production of a compound of interest.

US 5,374,627 [A] discloses a method comprising steps of contacting a living plant or plant part with an effective amount of acetic acid and allowing the effective amount of acetic acid

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to protect or prevent plant diseases and damages caused by agricultural pests thereby allowing to induce or to improve plant growth and plant production of biomass and compounds including therapeutically active compounds. The cited method is considered to anticipate the claimed invention because it comprises identical active steps drawn to treatment of living plant or plant parts with acetic acid as the presently claimed method. The plant which is protected or prevented from the plant diseases by effects of acetic acid is reasonably expected to demonstrate an improved production of biologically active compounds including compounds of interest which are intended in the claimed method.

Claims 1-5, 8, 10, 22, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,407,816 [B].

Claims are directed to a method for eliciting a compound having therapeutic activity from a plant or plant part wherein the method comprises the steps of contacting a living plant or plant part with an effective amount of acetic acid, allowing the acetic acid to induce or to improve production of a compound having therapeutic activity and recovering or collecting the compound. Some claims are further drawn to the use of particular "effective" amount of acetic acid or the amount of "0.1%" in the method for eliciting a compound having therapeutic activity from a plant or plant part. Some claims are further drawn to the use of water in an aqueous medium, to production of compounds having anti-cancer activity or to providing a library of recovered compounds in the method for eliciting therapeutically active compounds from a plant

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or plant part. Some claims are further drawn to recovering or collecting the compound by extracting or exuding the compound in an aqueous medium. Some claims are further drawn to the use of plants belonging to the species of *Taxus* including *Taxus media*, *Taxus baccata* or *Taxus cuspidata*.

US 5,407,816 [B] discloses a method for eliciting compounds having therapeutic activity such as taxol and taxane from plants belonging to the species of *Taxus* including *Taxus media*, *Taxus baccata* or *Taxus cuspidata* (col. 15, example 6 and table 5 at col. 24) wherein the method comprises the steps of contacting a living plant parts such as plant cell culture or callus culture with an effective amount of acetic acid in form of salt in an aqueous culture medium (table 2), allowing the acetic acid to induce or to improve production of taxol compounds by incubating plant parts or plant cell culture in the aqueous medium and recovering or collecting the compounds exuded in the aqueous medium (col. 15, item 5.2). The cited patent teaches that taxol compounds are characterized by anti-tumor or anti-cancer activity (col. 1, lines 26-30). The cited patent discloses the recovery of several taxol compounds (see tables 8-9) and, thus, it discloses a step of providing a library of recovered therapeutically active compounds. Although the acetic acid is applied in a form of acetate in the method of the cited patent, however it is reasonably expected that both acetic acid and acetate are effective in the same manner after being ionized in aqueous culture medium which is disclosed by the cited patent and which is required by the claimed method. Moreover, the cited patent clearly teaches that acetate or acetic acid salts are precursors in biosynthesis of therapeutically active compounds such as taxol and taxane, for

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example: see table 1.b. The cited patent teaches the use of a culture medium with 10 mg/L of sodium acetate (table 2) wherein the use of this particular concentration is effective in obtaining therapeutically active compounds such as taxol and taxanes as demonstrated by the method of the cited patent. Although the disclosed amount of acetate or acetic acid is not clearly identical to the claimed amount "0.1%", the claimed method is uncertain with either amount of aqueous medium or amount of plant material. Moreover, it is uncertain as claimed whether the claimed amount "0.1%" is a final concentration in a composition/system of the contacting step or whether the amount "0.1%" is concentration of a contacting composition/solution which is further dissolved in unidentified amount/volume of an aqueous medium. Thus, the disclosed amount of acetate or acetic acid in the method of the cited patent is considered to be substantially identical to the claimed amount as intended for the present invention particularly in view that the cited method demonstrates successful production and recovery of therapeutically effective compounds such as taxol and taxanes. Therefore, the cited method is considered to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-10, 22, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,407,816 [B] and US 5,620,875 [C] taken with Staba [U].

Claims are directed to a method for eliciting a compound having therapeutic activity from a plant or plant part wherein the method comprises the steps of contacting a living plant or plant part with an effective amount of acetic acid, allowing the acetic acid to induce or to improve production of a compound having therapeutic activity and recovering or collecting the compound. Some claims are further drawn to the use of water in an aqueous medium, to production of compounds having anti-cancer or anti-bacterial activity, to providing a library of recovered compounds in the method for eliciting a compound having therapeutic activity from a plant or plant part. Some claims are further drawn to the use of particular "effective" amount of acetic acid such as "0.1%" in the method for eliciting a compound having therapeutic activity from a plant or plant part. Some claims are further drawn to recovering or collecting the compound by extracting or exuding the compound in an aqueous medium. Some claims are further drawn to the use of plants belonging to the species of *Taxus* including *Taxus hicksii*, *Taxus media*, *Taxus baccata* or *Taxus cuspidata*.

The cited US 5,407,816 [B] is relied upon as explained above for the disclosure a method for eliciting compounds having therapeutic activity by contacting living plant material with acetic acid or acetic acid derivatives in amounts effective to induce or to improve production of therapeutically active compounds. The cited patent teaches that acetic acid derivatives including

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acetate (table 1.b) and auxins (table 3) are precursors and regulators of plant-derived therapeutically active compounds such as taxol and taxanes wherein these precursors and regulators allow to induce or to improve plant production of compounds of interest such as taxol and taxanes. In particular, the cited patent teaches that the use of plant parts such as cell culture or plant callus culture in the method for eliciting therapeutically active compounds but it is lacking disclosure related to the use of other parts of living plants comprising roots and/or leaves in a method for eliciting plant derived compounds of interest.

However, US 5,620,875 [C] is relied upon to demonstrate that the same biologically active or therapeutically active compounds such as taxol and taxanes are produced from other parts of plants such as living plant cuttings of *Taxus* which comprise roots and leaves (see abstract) in the culture media comprising acetic acid derivatives or auxins (col. 2, lines 42-43).

The disclosure of both cited patents US 5,407,816 [B] and US 5,620,875 [C] is related to the production of therapeutically active compounds such as taxol and taxanes by plants belonging to the genus of *Taxus*. But they are lacking disclosure with regard to variety of plants used for obtaining various plant derived compounds.

However, the reference by Staba et al. [U] is relied upon to demonstrate that various plants are used as sources for various therapeutically active compounds including antitumor and antimicrobial compounds (page 237) and that the acetic acid derivatives and/or auxins are important plant growth regulators generally used for plant growth and production (page 7).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to elicit or to produce the same or substantially similar therapeutically active compounds from any part of plants including plant cell culture and plant cuttings comprising roots and/or leaves with a reasonable expectation of success in obtaining therapeutically active compounds of interest because plant cells from any part of plants are capable to produce the same or similar compounds and they have the same or substantially similar metabolism to at least some extent as demonstrated by methods of both cited patents US 5,407,816 [B] and US 5,620,875 [C] with regard to production of taxol and taxanes. One of skill in the art would have been motivated to use various plants for producing therapeutically active compounds for the expected benefit of providing library of therapeutically active compounds and for the expected benefit of maximizing variety of recovered biologically active compounds as taught and/or suggested by Staba et al. [U]. One of skill in the art would have been motivated to adjust concentrations of culture medium components including concentrations of plant growth regulators and plant biosynthesis precursors in accordance with the amounts of plant parts or plant materials involved in the production method for the expected benefit of maximizing recovery of biologically active compounds derived from plant parts/materials.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

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Claims 6 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,407,816 [B], US 5,620,875 [C] and Staba [U] as applied to claims 1-5, 7-10, 22, 23 and 26 above, and further in view of US 4,871,574 [D].

Claims 1-5, 7-10, 22, 23 and 26 as explained above. Claims 6 and 24 are further drawn to the use of extracting/collecting step by macerating plant parts in the method for eliciting therapeutically active compounds.

The references US 5,407,816 [B], US 5,620,875 [C] and Staba [U] are relied upon as explained above. The cited references are silent with regard to macerating step in the method for eliciting therapeutically active compounds.

US 4,871,574 [D] teaches the use of macerating step in the method for eliciting therapeutically active compounds from plant parts. In addition, it also teaches that the use of acetic acid is allowed before or after or during macerating step (see Fig. 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a macerating step in a method for eliciting therapeutically active compounds from plant parts as taught or suggested by US 4,871,574 [D] with a reasonable expectation of success in obtaining the compounds of interest from plants parts/materials because maceration of plant parts/material is a known technique in the collection or recovery of plant therapeutically active and therapeutically valuable compounds. The presently claimed invention is uncertain with regard to the application of acetic acid or with regard to the structural relationship between various solutions or media comprising acetic acid during the steps of

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“allowing”, “extracting” and/or “macerating”. Nevertheless, the cited patent US 4,871,574 [D] demonstrates a successful recovery of therapeutically active compounds in the method for eliciting the therapeutically active compounds comprising application of acetic acid before, during or after macerating step. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Claims 11-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,407,816 [B], US 5,620,875 [C] and Staba [U] as applied to claims 1-5, 7-10, 22, 23 and 26 above, and further in view of Stevens et al. [IDS-C23] and US 3,810,990 [E].

Claims 1-5, 7-10, 22, 23 and 26 as explained above. Claims 11-15 and 25 are further drawn to the extracting of therapeutically active compounds from plant leaf cuticular material wherein material comprises wax and wherein the extracting solvents comprise methylene chloride or chloroform. Claims 17-21 are further drawn to assaying the therapeutically active compounds for antimicrobial activity by determining microbial rates of growth and/or inhibition.

The references US 5,407,816 [B], US 5,620,875 [C] and Staba [U] are relied upon as explained above for the disclosure of methods for eliciting various therapeutically active compounds from various parts of various plants contacted with or grown in the media comprising plant growth regulators and precursors of the therapeutically active compounds including acetic

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acid derivatives and/or auxins. The cited references US 5,407,816 [B], US 5,620,875 [C] and Staba [U] are lacking disclosure related to recovering therapeutically active compounds from plant leaf cuticular material.

However, the reference by Stevens et al. [IDS-C23] teaches the extracting of therapeutically active flavonoid compounds including quercetin from leaf cuticular material wherein the material is wax and wherein solvents comprise chloroform (abstract and page 805, col. 2, par. 1).

The cited US 3,810,990 [E] is relied upon to demonstrate the antimicrobial activity of flavonoid compounds including quercetin taught in the reference by Stevens et al. [U]. In addition, the cited US 3,810,990 [E] is also relied upon for the disclosure with regard to assaying the therapeutically active compounds/agents including flavonoids for antimicrobial activity by determining microbial rates of growth or inhibiting through the measurements of microbial turbidity and/or counting of microbial colonies in the media/solutions with therapeutically active compounds/agents (see example 7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to extract therapeutically active compounds from various plant parts or materials including plant leaf cuticular materials with a reasonable expectation of success in obtaining the compounds of interest including antimicrobial compounds because it has been demonstrated in the prior art that the plant leaf cuticular materials including wax, which is presently claimed, is a known source of biologically active compounds as taught by Stevens et al.

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[IDS-C23]. One of skill in the art would have been motivated to produce various plant derived therapeutically active compounds including flavonoids of the reference by Stevens et al. [U] by growing plants or plant parts in media comprising plant growth regulators and/or precursors comprising acetic acid derivatives or auxins which are generally used for growing various beneficial plants for the expected results in maximizing production of therapeutically active compounds of interest by various plants as taught and suggested by the cited prior art {US 5,407,816 [B], US 5,620,875 [C], Staba [U]}. The methods for assaying antimicrobial activity of various compounds or agents which are presently claimed are very well known techniques in the field of microbiology as adequately demonstrated by US 3,810,990 [E]. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova



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VERA AFREMOVA

October 28, 2002.

PATENT EXAMINER